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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,955	05/04/1999	ROBERT JAMES MASON	A-67653/DCA/	3606

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EXAMINER	
BRUMBACK, BRENDA G	
ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/230,955	Applicant(s) MASON ET AL.	
	Examiner Brenda G. Brumback	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5 and 7* is/are allowed.

6)☒ Claim(s) *1-4 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on 07/08/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/230,955 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed 04/05/2002 has been entered. Claims 1, 4, and 8 were amended. Claims 1-5, and 7-8 are pending and under examination on the merits.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Porta et al. for the reasons of record. Applicant's arguments with the English translation of Porta et al. and the accompanying Jha et al. and Epenetos et al. references have been considered but they are not persuasive for the reasons outlined in the Advisory Action mailed 06/04/2002 and reiterated herein.

Applicant argues that Porta et al. do not anticipate the present claims, but rather teach away by teaching that Epenetos et al. use monoclonal antibodies for diagnosis of other than cervical neoplasia and that Jha et al. teach that monoclonal antibodies did not differentiate normal and neoplastic tissue. However, Porta et al. teach that monoclonal antibodies have been successfully used by others to screen for neoplasia of the cervix by staining cells in a cervical smear sample. While Porta et al. do teach that Jha et al. reported that one particular panel of monoclonal antibodies were not successful in differentiating neoplastic and normal cells, they also teach that other researchers have successfully used monoclonal antibodies for differentiation of neoplastic and normal cells in cervical smear samples. Applicant is

reminded that the claimed method is not drawn to the specific monoclonal antibody panel used by Jha, but rather is drawn to a method of differentiating neoplastic or premalignant cells from normal cells using a panel of two or more of any monoclonal antibodies. Applicant is reminded that absolute predictability is not required, but rather a reasonable expectation of success. Taken as a whole, the teachings of Porta et al. support such a reasonable expectation of success.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Smedts et al. for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive for the reasons set forth in the Advisory Action mailed 06/04/2002 and reiterated herein.

Applicant argues that the monoclonal antibodies used by Smedts et al. were raised against synthetic antigens and thus Smedts et al. does not anticipate the claimed invention, which uses monoclonal antibodies raised against antigens present on normal cells. While Smedts et al. do teach that the panel of antibodies used were raised against synthetically made keratins, the keratins against which the monoclonal antibodies were raised are also present on normal cells. Even if the antigens used by Smedts et al. to raise the monoclonal antibodies were structurally different from the keratins present on normal cells, absent some evidence to the contrary, the antibodies used by Smedts et al. would be expected to have the same reactivity as monoclonal antibodies raised against keratins derived from natural sources. The panel of monoclonal antibodies used in the claimed method would thus be viewed as a product-by-process. Even though the products are defined by the claimed process, determination of patentability is based on the product itself. The claimed products and methods are not patentable over those of the prior art absent any distinct difference in the products or methods themselves (see MPEP § 2113).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 2 stand rejected under 35 U.S.C. 103(a) as obvious over Smedts et al. for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive for the reasons outlined in the Advisory Action mailed 06/04/2002 and reiterated herein.

Applicant argues that the method of Smedts et al. would not work for cervical smear samples because Smedts et al. teach staining cells which have kept their original structure; however, one of skill in the art at the time the invention was made would have expected monoclonal antibodies to react with the same cellular antigens regardless of whether the cells retained their original tissue structure or were smeared onto a slide. Applicant has provided no evidence to the contrary. Argument in the absence of evidence is not persuasive.

Applicant argues that for the method of Smedts et al. to be effective, the type of cell being tested must be known. The relevance of this argument, however, is not apparent, as the same would seem to be true of applicant's claimed method, which is drawn specifically to a smear of cervical cells.

Claim 8 stands rejected under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over either of Porta et al. or Smedts et al. for the reasons of record. Applicant's arguments filed 04.05.02 have been fully considered but they are not persuasive for the reasons outlined in the Advisory Action mailed 06/04/2002 and reiterated herein.

Applicant argues that neither Porta et al. nor Smedts et al. teaches a specific binding substance able to bind to an antigen of cervical tissue to which a hybridoma selected from those deposited can bind. Applicant's claims are not drawn to monoclonals which bind the specific epitopes bound by the monoclonals of the deposited hybridomas, but rather are drawn any monoclonal that binds any part of any

antigen that binds any of the monoclonals produced by any of the deposited hybridomas. Applicant has provided no evidence that the monoclonal antibodies used by Porta et al. or Smedts et al. bind a different antigen. Once again, argument in the absence of evidence is not persuasive.

Claim Rejections - 35 USC § 112

Claims 1-4 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record. Applicant's arguments filed 04/05/2002 have been fully considered but they are not persuasive for the reasons set forth in the Advisory Action mailed 06/04/2002 and reiterated below.

Applicant makes the general statement that it is clear from the specification as filed that the staining pattern is significantly different between premalignant and normal specimens; however, applicant has neither addressed any of the apparent discrepancies between the data and this conclusion which were set forth in the previous Office action nor addressed the differences in the scope of the invention as claimed (two or more antibodies) and the data (a panel of five antibodies) presented in the specification.

The rejection of claims 1, 2, and 4 under 35 U.S.C. 112, first paragraph, (new matter) for the phrase "each antibody having specificity for a different antigen of said sample relative to the other antibodies in said sample" is withdrawn pursuant to applicant's amendment of the claims; however, see the new grounds of rejection which follow.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended claim 1 to recite "having different specificities and raised against antigens present on normal cervical tissue". Applicant's comments pointing to support for the amendment at pages 4 and 17 are noted; however, support was not found for the proposed amendment as indicated. Applicant is invited to further clarify how the referenced portion provides support for the proposed amendment of claim 1 or to point to other support in the specification as a possible means of resolving the issue.

The rejection of claims 1, 2, and 4 under 35 U.S.C. 112, second paragraph, is withdrawn pursuant to applicant's amendment thereof.

Conclusion

Claims 5 and 7 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB
July 26, 2002

Brenda Brumback
Primary Examiner